

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to All Actions

DECLARATION OF GENEVIEVE M. ZIMMERMAN

Genevieve M. Zimmerman, being first duly sworn, deposes and declares as follows:

1. My name is Genevieve M. Zimmerman and I am a Partner with the Meshbesh & Spence Ltd. law firm. I am a member of the Court appointed Co-Lead Counsel in the above entitled matter.
2. I submit this declaration in support of Plaintiffs' Response Opposing Defendants' Motion for Summary Judgment. Unless otherwise stated, the facts set forth herein are based upon my personal knowledge, information, and belief.
3. Attached hereto as Exhibit 1 is a true and correct copy of a photograph of the warning label on a Bair Hugger Model 200.
4. Attached hereto as Exhibit 2 is a true and correct copy of an internal clinical trial protocol titled *The effect of prewarming by a Bair Paws gown on redistribution hypothermia in patients undergoing total joint replacement or colorectal surgery*, dated September 6, 2007, bearing bates numbers 3MBH00982867-85.
5. Attached hereto as Exhibit 3 is a true and correct copy of 3MBH00001389.

6. Attached hereto as Exhibit 4 is a true and correct copy of Kurtz, Steven M., et. al., *Economic Burden of Periprosthetic Joint Infection in the United States*, J. OF ARTHROPLASTY, Vol. 27, No. 8 Supp. 1 (2012).
7. Attached hereto as Exhibit 5 is a true and correct copy of Wagner, Jennifer A., et. al. *Using Cleanroom Technology: Improving Operating Room Contamination Control*, ASHRAE (February 2014).
8. Attached hereto as Exhibit 6 is a true and correct copy of the Deposition of Dr. Michael Mont, taken on July 28, 2017 in Cleveland, OH.
9. Attached hereto as Exhibit 7 is a true and correct copy of the Deposition of Dr. Richard Wenzel, taken on August 4, 2017 in Washington, D.C.
10. Attached hereto as Exhibit 8 is a true and correct copy of Stocks GW, Self SD, et.al. *Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery*, AMERICAN JOURNAL OF INFECTION CONTROL (2010) 38(3):199-204.
11. Attached hereto as Exhibit 9 is a true and correct copy of Memarzadeh and A. P. Manning, *Comparison of Operating Room Ventilation Systems in the Protection of the Surgical Site*, ASHRAE TRANS., vol. 108, pp. 454964552, 2002.
12. Attached hereto as Exhibit 10 is a true and correct copy of *Operative Environment, International Consensus of Orthopedic Surgeons*, J ORTHOP RES 32:S60-S80 (2014).
13. Attached hereto as Exhibit 11 is a true and correct copy of Darouiche, R., Green, D., Harrington, M., Ehni, B., Kougias, P., Bechara, C., & O'Connor, D. (2017). *Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial*. INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY, 38(1), 3-10. doi:10.1017/ice.2016.240).
14. Attached hereto as Exhibit 12 is a true and correct copy of Raval, et al. *Real-time monitoring of non-viable airborne particles correlates with airborne colonies and represents an acceptable surrogate for daily assessment of cell-processing cleanroom performance*, CYTOTHERAPY (2012).

15. Attached hereto as Exhibit 13 is a true and correct copy of Zheng, et al.
Concentrations and Size Distributions of Airborne Particulate Matter and Bacteria in an Experimental Aviary Laying-Hen Chamber, JOURNAL OF THE AMERICAN SOCIETY OF AGRICULTURAL AND BIOLOGICAL ENGINEERS (2013).
16. Attached hereto as Exhibit 14 is a true and correct copy of Seal and Clark.
Electronic Particle Counting for Evaluating the Quality of Air in Operating-Theaters - a Potential Basis for Standards, THE JOURNAL OF APPLIED BACTERIOLOGY (1990).
17. Attached hereto as Exhibit 15 is a true and correct copy of 3MBH00050770-71.
18. Attached hereto as Exhibit 16 is a true and correct copy of the deposition of Dr. Daniel Sessler, taken on January 11, 2017 in Cleveland, OH.
19. Attached hereto as Exhibit 17 is a true and correct copy of the deposition of Corporate Representative Al Van Duren, taken in Minneapolis, MN on March 7, 2017.
20. Attached hereto as Exhibit 18 is a true and correct copy of 3MBH00580475.
21. Attached hereto as Exhibit 19 is a true and correct copy of the deposition of Thomas Kuehn, Ph.D., taken in Minneapolis, MN on July 10, 2017.
22. Attached hereto as Exhibit 20 is a true and correct copy of an email exchange between Counsel for Defendants and Counsel for Plaintiffs, dated September 19, 2016.
23. Attached hereto as Exhibit 21 is a true and correct copy of 3MBH01485746.
24. Attached hereto as Exhibit 22 is a true and correct copy of 3MBH00556461.
25. Attached hereto as Exhibit 23 is a true and correct copy of 3MBH00144055.
26. Attached hereto as Exhibit 24 is a true and correct copy of 3MBH01260231.
27. Attached hereto as Exhibit 25 is a true and correct copy of 3MBH00814685.
28. Attached hereto as Exhibit 26 is a true and correct copy of 3MBH01975265.

29. Attached hereto as Exhibit 27 is a true and correct copy of Michael Buckø's Expert Report.
30. Attached hereto as Exhibit 28 is a true and correct copy of Said Elghobashi's Expert Report.
31. Attached hereto as Exhibit 29 is a true and correct copy of websites previously promoted and registered to the Blackwell Burke law firm.
32. Attached hereto as Exhibit 30 is a true and correct copy of Reed M, Kimberger O, McGovern PD, Albrecht MC, *Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions*, AANA JOURNAL (2013 Aug);81(4):275-80.
33. Attached hereto as Exhibit 31 is a true and correct copy of the HICPAC Record of Proceedings, Nov. 5-6, 2015.
34. Attached hereto as Exhibit 32 is a true and correct copy of *ECRI Update: You're Getting Warm: Uncovering Forced-air Warming Units*
35. Attached hereto as Exhibit 33 is a true and correct copy of December 2016 3M Letter to FDA re filter.
36. Attached hereto as Exhibit 34 is a true and correct copy of 3MBH01617179.
37. Attached hereto as Exhibit 35 is a true and correct copy of 3MBH001534468.
38. Attached hereto as Exhibit 36 is a true and correct copy of the Deposition of Theodore Holford, taken on July 18, 2015 in Hartford, Connecticut.
39. Attached hereto as Exhibit 37 is a true and correct copy of Dr. Holford's Expert Report.
40. Attached hereto as Exhibit 38 is a true and correct copy of Mark Albrecht's deposition, which was taken over two days (October 7, 2016 and November 12, 2016). Both days were taken in Minneapolis, MN.

41. Attached hereto as Exhibit 39 is a true and correct copy of Christopher Nachtsheim's deposition, taken on November 29, 2016 in Minneapolis, MN.
42. Attached hereto as Exhibit 40 is a true and correct copy of Paul McGovern's deposition, taken over two days (January 4-5, 2017) in London, U.K.
43. Attached hereto as Exhibit 41 is a true and correct copy of Jonathan Samet's deposition, taken over two days (July 11 and August 8, 2017) in Los Angeles, CA.
44. Attached hereto as Exhibit 42 is a true and correct copy of Jonathan Borak's Expert Report.
45. Attached hereto as Exhibit 43 is a true and correct copy of Dr. Jonathan Samet's Expert Report.
46. Attached hereto as Exhibit 44 is a true and correct copy of Legg, Cannon, and Hamer, *Do forced air patient warming devices disrupt unidirectional downward airflow?*, THE JOURNAL OF BONE AND JOINT SURGERY (2012).
47. Attached hereto as Exhibit 45 is a true and correct copy of Legg and Hamer *Forced-air patient warming blankets disrupt unidirectional airflow*, THE JOURNAL OF BONE AND JOINT SURGERY (2013).
48. Attached hereto as Exhibit 46 is a true and correct copy of the Deposition of Andrew Legg, taken on December 1, 2016 in Sheffield, U.K.
49. Attached hereto as Exhibit 47 is a true and correct copy of Avidan, et al., *Convection warmers—not just hot air*, 52 ANESTHESIA 1073-1076 (1997)..
50. Attached hereto as Exhibit 48 is a true and correct copy of Beavers, *Acinetobacter Infections among Hospitalized Patients in Kentucky*, 42(2) KENTUCKY EPIDEMIOLOGIC NOTES & REPORTS 165 (2007).
51. Attached hereto as Exhibit 49 is a true and correct copy of Bernards, et al. *Persistent Acinetobacter Baumannii? Look Inside Your Medical Equipment*, 25 INFECT. CONTROL HOSP. EPIDEMIOLOGY 1002-1004 (2004).

52. Attached hereto as Exhibit 50 is a true and correct copy of Gjola, et al. *Don't Forget to Change the Bair Hugger Filter*, Stanford Medical School (2009).
53. Attached hereto as Exhibit 51 is a true and correct copy of Mark Albrecht, Robert L. Gauthier, and David Leaper, MD, ChM, FRCS, FACS, *Forced-air Warming: a source of airborne contamination in the operating rooms?* ORTHOPEDIC REVIEWS (2009).
54. Attached hereto as Exhibit 52 is a true and correct copy of Oguz, Ruken et al., *Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial*, J CLIN ANESTH , Volume 38 , 160 ó 164.
55. Attached hereto as Exhibit 53 is a true and correct copy of Moretti B, Larocca AMV, Napoli C, et al. *Active Warming Systems To Maintain Perioperative Normothermia In Hip Replacement Surgery: A Therapeutic Aid Or A Vector Of Infections?* J HOSP INFECT (2009); 73:58-63.
56. Attached hereto as Exhibit 54 is a true and correct copy of the deposition of Dr. Andrea Kurz, taken on January 12, 2017 in Cleveland, OH.
57. Attached hereto as Exhibit 55 is a true and correct copy of Brown, Michael J., et.al., *Intraoperative Hypothermia and Surgical Site Infections in Patients with Class I/Clean Wounds: A Case Control Study*, J. AM. COLLEGE SURG. (2016).
58. Attached hereto as Exhibit 56 is a true and correct copy of Kumar Belani, MBBS, MS, Mark Albrecht, MStat, MBA, BSME, Paul D. McGovern, BSc, MBBS, MRCS, PGCME, FHEA, Mike Reed, MBBS, MD, FRCS, (T&O), and Christopher Nachtsheim, PhD, *Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance*, ANESTHESIA & ANALGESIA (2012).
59. Attached hereto as Exhibit 57 is a true and correct copy of Wood, Moss, Keenan, Reed, and Leaper, *Infection control hazards associated with the use of forced air warming in operating theatres*, JOURNAL OF HOSPITAL INFECTION (2014)..

60. Attached hereto as Exhibit 58 is a true and correct copy of Tumia, et al., *Convection Warmers—a possible source of contamination in laminar airflow operating theaters?* 52 J. HOSP. INF. 1716174 (2002).
61. Attached hereto as Exhibit 59 is a true and correct copy of P.D. McGovern, et. al. *Forced-air warming and ultra-clean ventilation do not mix*, THE JOURNAL OF BONE & JOINT SURGERY (November 2011).
62. Attached hereto as Exhibit 60 is a true and correct copy of Sessler DI, Olmsted RN, Kuelpmann R. *Forced-Air Warming Does Not Worsen Air Quality In Laminar Flow Operating Rooms*. ANESTH ANALG. 113(6):1416-21.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Minneapolis, MN, this 3rd day of October, 2017.

/s/ Genevieve M. Zimmerman

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